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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
LI, RUIXIANG	

ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 02/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/727,739	SHERIDAN ET AL.	
	Examiner	Art Unit	
	Ruixiang Li	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 June 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3 and 12-20* is/are pending in the application.

4a) Of the above claim(s) *16-20* is/are withdrawn from consideration.

5)☒ Claim(s) *3* is/are allowed.

6)☒ Claim(s) *1,2,12 and 13* is/are rejected.

7)☒ Claim(s) *14 and 15* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Status of Application, Amendments, and/or Claims

The amendment filed on November 21, 2003 has been entered in full. Claim 1 has been amended. Claims 16-20 have been added. Claims 1-3 and 12-15 are under consideration. Newly added claims 16-20 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicants' request for rejoinder is noted, and will be considered when the product claims are found allowable (see below for detailed information).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Withdrawn Objections and/or Rejections

The rejection of claim 1 under 35 U.S.C. 102(b) as being anticipated by Moore et al. (General and Comparative Endocrinology, 98:253-261, 1995), as set forth at pages 2-3 of the previous Office Action (Paper No. 28, August 21, 2003), has been withdrawn in view of applicants' amendment to the claim.

The rejection of claims 12 and 13 under 35 U.S.C. 103(a) as being unpatentable over Moore et al. (General and Comparative Endocrinology, 98:253-261, 1995), in view of Hobart et al. (EU 46669 A1, March 3, 1982), as set forth at pages 3-4 of the previous Office Action (Paper No. 28, August 21, 2003), has been withdrawn in view of applicants' amendment to claim 1, which claims 12 and 13 depend from.

The objection of claim 3, as set forth at page 4 of the previous Office Action (Paper No. 28, August 21, 2003), has been withdrawn.

Claim Rejections Under 35 USC § 112, 1st paragraph

(i). The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

(ii). Claims 1, 12, and 13 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for polypeptides or fusion proteins comprising SEQ ID NOS: 2 and 15-19, does not reasonably provide enablement for an analog of SEQ ID NO: 15 that has an amino acid sequence at least 85% identical to SEQ ID

NO: 15 or a fusion protein comprising such an analog. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The factors that are considered when determining whether a disclosure satisfies enablement requirement include: (i) the quantity of experimentation necessary; (ii) the amount of direction or guidance presented; (iii) the existence of working examples; (iv) the nature of the invention; (v) the state of the prior art; (vi) the relative skill of those in the art; (vii) the predictability or unpredictability of the art; and (viii) the breadth of the claims. *Ex Parte Forman*, 230 USPQ 546 (Bd Pat. App. & Int. 1986); *In re Wands*, 858 F. 2d 731, 8 USPQ 2d 1400 (Fed. Cir. 1988).

Applicants' amendment to claim 1 has removed the functional limitation, "wherein the somatostatin polypeptide binds to a somatostatin receptor", from the claim, rendering the claim and its dependent claims unenabled.

Claim 1, in part c, recites an analog of SEQ ID NO: 15 that has an amino acid sequence at least 85% identical to SEQ ID NO: 15, whereas claims 12 and 13 are drawn to, in part, a fusion polypeptide comprising such an analog. However, other than SEQ ID NO: 15 and its major fragments set forth in SEQ ID NOS: 16-19, the disclosure fails to provide sufficient guidance or working examples regarding the structural and functional requirements commensurate in scope with what is

encompassed by the instant claims. The disclosure has not shown (i) which portions of SEQ ID NO: 15 are critical to the activity of the claimed polypeptide; and (ii) what modifications (e.g., substitutions, deletions or additions) one can make to SEQ ID NO: 15 will result in protein mutants with the same functions as the protein of SEQ ID NO: 15. The state of the art (See, e.g., Ngo, et al, *The Protein Folding Problem and Tertiary Structure Prediction*, 1994, Merz, et al. (ed.), Birkhauser, Boston, MA, pp. 433 and 492-495) is such that the relationship between sequence of a protein and its activity is not well understood and is not predictable. Excising out portions of a protein or modifications to a protein, e.g., by substitutions or deletions, would often result in deleterious effects to the overall activity and effectiveness of the protein. Thus, the disclosure fails to teach an artisan how to make those analogues that have the same activity as that of SEQ ID NO: 15 and fails to teach an artisan how to use those analogues of SEQ ID NO: 15 that do not have the activity of SEQ ID NO: 15.

Accordingly, the disclosure fails to enable such a genus of analogues of SEQ ID NO: 15 and fusion proteins comprising such an analogue. It would require undue experimentation for one skilled in the art to use the claimed genus of molecules embraced by the instant claims.

(iii). Claims 1, 12, and 13 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof.

Claim 1, in part c, recites an analog of SEQ ID NO: 15 that has an amino acid sequence at least 85% identical to SEQ ID NO: 15, whereas claims 12 and 13 are drawn to, in part, a fusion polypeptide comprising such an analog. Thus, the only factor present in the claim is a partial structure in the form of a recitation of percent identity. The claims do not require that the polypeptide possess any particular biological activity, nor any particular conserved structure, or other disclosed distinguishing feature.

However, other than SEQ ID NO: 15 and its major fragments set forth in SEQ ID NOS: 16-19, the specification fails to provide sufficient description for an analog of SEQ ID NO: 15 that is at least 85% identical to SEQ ID NO: 15 and a fusion polypeptide comprising such an analog. There is no description in the specification of the conserved regions that are critical to the structure and function of the genus claimed. There is no description of the amino acid residues at which variability may be tolerated and there is no information regarding the relation of structure to function. Furthermore, the prior art does not provide compensatory structural or correlative

teachings to enable one skilled in the art to identify the encompassed polypeptides as being identical to those instantly claimed. Accordingly, in the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the claimed analogues and fusion protein comprising such an analog.

Therefore, only an isolated polypeptide comprising SEQ ID NO: 15 or its major fragments set forth in SEQ ID NOS: 16-19 and a fusion protein comprising the polypeptide, but not the full breadth of the claims meets the written description provision of 35 U.S.C. §112, first paragraph.

Claim Rejections Under 35 U. S. C. § 102 (b)

The rejection of claim 2 under 35 U.S.C. 102(b) as being anticipated by Moore et al. (General and Comparative Endocrinology, 98:253-261, 1995), as set forth at pages 2-3 of the previous Office Action (Paper No. 28, August 21, 2003), remains.

Applicants have not amended the claim to overcome the rejection set forth at page 3 (2nd paragraph) of the previous Office Action (Paper No. 28, August 21, 2003). Since the somatostatin polypeptide of preprosomatostatin II taught by Moore et al. comprises SEQ ID NO: 2 (the last 14 amino acid sequence of SEQ ID NO: 15 or SEQ ID NO: 16), the reference of Moore et al. meets the limitations of claim 2.

Claim Objection

Claims 14 and 15 are objected to as being dependent upon a rejected base claim (claims 12 and 13, respectively), but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruixiang Li whose telephone number is (571) 272-0875. The examiner can normally be reached on Monday-Friday, 8:30 am-5:00 pm. If

attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (571) 272-0871.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [yvonne.eyler@uspto.gov]. All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

Ruixiang Li
Examiner
January 26, 2004

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SUPERVISORY PATENT EXAMINER
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